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| PREVAILED | Roll Call No. _____ |
| FAILED | Ayes _____ |
| WITHDRAWN | Noes _____ |
| RULED OUT OF ORDER | |

# HOUSE MOTION ____

MR. SPEAKER:

I move that Engrossed Senate Bill 10 be amended to read as follows:

Page 1, delete lines 1 through 12, begin a new paragraph and insert:

"SECTION 1. IC 12-15-35-28 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 28. The board ~~has~~ **shall advise the board concerning** the following: ~~duties:~~

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are

educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

SECTION 2. IC 12-15-35-35 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 35. (a) As used in this section, "single source drug" means a covered outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors

operating under the new drug application.

(b) Before the approval or implementation of a prior approval program for outpatient single source drugs, or a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the program must meet the following conditions:

~~(1) An outpatient single source drug may not be placed on prior approval or restricted in its use for other than medical reasons.~~

~~(2)~~ **(1)** Before a single source drug is placed on prior approval or restricted in its use, the **office, together with the** board, must hold a public hearing under IC 4-22 at least ninety (90) days before taking the action.

~~(3)~~ **(2)** The board must provide evidence that placing a single source drug on prior approval or restricting its use will not impede the quality of patient care and that the single source drug is subject to clinical abuse or misuse before the board recommends that the drug be placed on prior approval or restricted in its use.

~~(4)~~ **(3)** Any single source drug placed on prior approval or restricted in its use will be reconsidered for removal from its restricted status by the board from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

~~(5)~~ **(4)** Any prior approval program must provide either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

~~(6)~~ **(5)** Any prior approval program or restriction on the use of a single source drug may not be applied to prevent acceptable medical use for appropriate off-label indications.

(c) The DUR board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

SECTION 3. IC 12-15-35-45 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 45. (a) The chairman of the board, subject to the approval of the board members, may appoint an advisory committee to make recommendations to the board on the development of a Medicaid outpatient drug formulary.

(b) If the office decides to establish a Medicaid outpatient drug formulary, the formulary shall be developed by the DUR board.

**(c) If a managed care organization that has a contract with the office decides to establish an outpatient drug formulary, the formulary must be developed under IC 27-13-38 and is not subject to this chapter.**".

Renumber all SECTIONS consecutively.

(Reference is to ESB 10 as printed March 30, 1999.)

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Representative Welch